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MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 300 MCLEAN, VA 22102			EXAMINER PYZOSHA, MICHAEL J	
			ART UNIT	PAPER NUMBER
			2137	

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/822,261

**Applicant(s)**

KNAUS ET AL.

**Examiner**

Michael Pyzocha

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 46-59 is/are pending in the application.
- 4a) Of the above claim(s) 30-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 46-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>see attachment</u> . | 6) <input type="checkbox"/> Other: _____  |

01082002, 08012002, 08192002

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**DETAILED ACTION**

1. Claims 1-59 are pending.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-29, 46-59, are drawn to secure access to medical records, classified in class 713, subclass 193.

- II. Claims 30-45, are drawn to a medical records database, classified in class 707, subclass 9.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility because it can be used for the access of documents from any remote computer, not necessarily the database of invention II. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by

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their different classification, restriction for examination purposes as indicated is proper.

#### ***Response to Arguments***

4. Applicant's arguments have to restriction have been considered. As per the argument that Examiner failed to establish a *prima facie* case for a restriction because "serious burden" has not been shown, it is brought to the applicant's attention that MPEP § 808.02 states three reasons for restriction, and the one must be shown. The three reasons are: separate classification; a separate status in the art when they are classifiable together; and a different field of search. In this case it is shown above that the inventions require different classification.

As per the argument to include claims 46-59 in Group I, has been considered and claims 46-59 are now included in Group I as in the above restriction.

#### ***Claim Objections***

5. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new

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claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 12 has been renumbered claim 11.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 5-11, 16-17, 46-47, 51-53, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne et al (U.S. 5,867,821) and further in view of Shear (U.S. 4,827,508).

As per claim 1, Ballantyne et al discloses a broad-band, computer-based networked system comprising: the medical records are obtained and electronically compiled from a plurality of sources (see figure 1); one or more medical records of the collection possess a characteristic of non-repudiation such that information contained within said medical records is verified as accurate and correct (see column 12 lines 48-55); the medical

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record of a person is transmissible in whole or in part only to that person and others authorized by that person (see column 8 lines 43-65); each medical record can be supplemented with additional information (see column 12 lines 24-31); and additional medical records for additional persons may be added to the collection (see column 12 lines 9-24); a secure access for allowing each person to access only their own medical record; and at least another secure access for allowing said others authorized to access only that person's medical record (see column 8 lines 14-65).

Ballantyne et al fails to disclose the collection of records being encrypted.

However, Shear teaches a collection of encrypted records (see column 4 lines 65-68).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use Shear's method of encrypting records to encrypt Ballantyne et al' collection of medical records.

Motivation to do so would have been to prevent excessive copying (see Shear column 5 lines 49-56).

As per claim 2, the modified Ballantyne et al and Shear system discloses the medical records are electronically complied by direct input or digital scanning of written information into

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a compute-readable format (see Ballantyne et al column 12 lines 9-47) .

As per claim 3, the modified Ballantyne et al and Shear system discloses the sources are selected from the group consisting of hospitals, clinics, physician's offices, pharmacies and combinations thereof (see Ballantyne et al figure 1) .

As per claim 5, the modified Ballantyne et al and Shear system discloses the medical record for each person contains one or more of: a table of contents, an index, a source notation for information contained within the medical record, an electronic search tool, annotations for errors, linked annotations for errors, treatment options, health care choices, verification standards, and news items relevant to the information in the medical record (see Ballantyne et al column 7 lines 7-65 and Shear column 11 lines 38-49) .

As per claim 6, the modified Ballantyne et al and Shear system discloses the secure access and the another secure access comprise passwords or encryption keys (see Ballantyne et al figures 9A-9B and Shear column 5 lines 49-63) .

As per claim 7, the modified Ballantyne et al and Shear system discloses the others authorized are selected from the



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group consisting of physicians, nurses, hospitals and health care institutions (see Ballantyne et al column 8 lines 20-30).

As per claim 8, the modified Ballantyne et al and Shear system discloses all of the medical records of the collection possess the characteristic of non-repudiation (see Ballantyne et al column 12 lines 48-55).

As per claim 9, the modified Ballantyne et al and Shear system discloses the non-repudiated medical record is primary for treatment of the patient to whom said non-repudiated medical record pertains (see Ballantyne et al column 12 lines 9-47).

As per claim 10, the modified Ballantyne et al and Shear system discloses each medical record is certified as accurate (see Ballantyne et al column 12 lines 9-47).

As per claim 11, the modified Ballantyne et al and Shear system discloses each certified medical record is certified as accurate by the patient, by the source from which said each medical record was obtained, by a system provider or by a combination thereof (see Ballantyne et al column 12 line 9-47).

As per claim 16, the modified Ballantyne et al and Shear system discloses a fee which is assessed for each access to a medical record (see Shear column 3 lines 3-14).

As per claim 17, Ballantyne et al and Shear fail to disclose a maintenance fee. However, Official Notice is taken

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that it would have been obvious to one skilled in the art to assess a maintenance fee for the medical records. Motivation to do so would have been to pay for holding, correcting, and supplying the medical records.

As per claim 46, the modified Ballantyne et al and Shear system discloses a computer system for management of medical records that are not subject to repudiation comprising a database of medical records pertaining to one or more subjects; a receiver for receiving information pertaining to said medical records from one or more senders; a process for verifying that the information received is accurate and correct by at least vetting said information; a process for authorizing said senders and said additional receivers according to a set of rules wherein said set of rules is designated by said subjects; and a transmitter for transmitting at least a portion of said medical records to one or more additional receivers (see Ballantyne et al column 8 lines 9-65 and column 12 lines 9-47 and Shear column 6 lines 49-63).

As per claim 47, the modified Ballantyne et al and Shear system discloses the database is a secure database (see Ballantyne et al column 8 lines 10-65).

As per claim 51, the modified Ballantyne et al and Shear system discloses the receiver is selected from the group

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consisting of: modem, cellular receiver, infrared receiver, Ethernet card, facsimile, cable modem, satellite receiver, optical, analog receiver, Internet hub, and web-server (see Ballantyne et al column 9 lines 1-15).

As per claim 52, the modified Ballantyne et al and Shear system discloses the transmitter is selected from the group consisting of: modem, cellular receiver, infrared receiver, Ethernet card, facsimile, cable modem, satellite receiver, optical, analog receiver, Internet hub, and web-server (see Ballantyne et al column 4 lines 65-67).

As per claim 53, the modified Ballantyne et al and Shear system discloses the process of authorizing comprises public key encryption, digital signatures, biometrics, certificate authorities, or user passwords (see figures 9A-9B, 11C and Shear column 5 lines 49-63).

As per claim 57, the modified Ballantyne et al and Shear system discloses the database is administer by a service provider other than said subjects, senders, and receivers (see Shear column 4 lines 9-20).

As per claim 59, the modified Ballantyne et al and Shear system discloses the medical records are owned by said subjects (see column 7 line 66 through column 8 line 9).

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8. Claims 20-22, 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker ("PCASSO: A Model for Safe Use of the Internet in Healthcare") and further in view of Ballantyne et al.

As per claim 20, Baker discloses a broad-band computer-based networked system for individual control and management of electronic medical records comprising a plurality of medical records representing a plurality of persons wherein said plurality complies with a federal standard of privacy and security (see Baker pages 34-35).

Baker fails to disclose at least one medical record of the plurality is not subject to repudiation.

However, Ballantyne et al teaches a medical record not subject to repudiation (see column 12 lines 48-55 where the signature ensures non-repudiation).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use Ballantyne et al's method of non-repudiation in Baker's medical record distribution system.

Motivation to do so would have been for authorization to change records (see Ballantyne et al column 12 lines 48-55).

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As per claim 21, the modified Baker and Ballantyne et al system discloses allowing for certification of said medical records (see Ballantyne et al column 12 lines 48-55).

As per claim 22, the modified Baker and Ballantyne et al system discloses the certification represents a predetermined degree of completeness, accuracy or both to said medical records (see Ballantyne et al column 12 lines 48-55).

As per claim 26, the modified Baker and Ballantyne et al system discloses the non-repudiated medical record is primary for treatment of the patient to whom said non-repudiated medical record pertains (see Ballantyne et al column 12 lines 9-47).

As per claims 27-29 and 48-50, the modified Ballantyne et al, Shear, and Baker system discloses the collection complies with privacy and security standards (see Bates page 34 column 2).

9. Claims 4, 12-15, 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Ballantyne et al and Shear system as applied to claims 1, 46 above, and further in view of Baker ("PCASSO: A Model for Safe Use of the Internet in Healthcare").

As per claim 4, the modified Ballantyne et al and Shear system fails to disclose medical records being transmittable through the Internet.

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However, Baker teaches medical records being transmittable through the Internet (see page 34 column 1).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use Baker's method of transmitting medical records in the medical record distribution system of Ballantyne et al and Shear.

Motivation to do so would have been that the Internet can support an information access and distribution model (see Baker page 34 column 1).

As per claim 12, the modified Ballantyne et al, Shear, and Baker system discloses the collection comprises medical records of more than 100,000 persons (see Baker page 34 column 3).

As per claims 13-15 and 48-50, the modified Ballantyne et al, Shear, and Baker system discloses the collection complies with privacy and security standards (see Bates page 34 column 2).

10. Claims 18-19, 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Ballantyne et al and Shear system as applied to claims 1 and 46 above, and further in view of Arpeggio ("Checking Database Integrity").

As per claims 18-19, the modified Ballantyne et al and Shear system fails to disclose vetted medical records containing one or more of: corrections of incorrect information, notations

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of incorrect information, notations of anomalies, linking of errors, linking of anomalies, notation of discrepancies, linking of discrepancies, and combinations thereof.

However, Arpeggio teaches such vetted records (see pages 1-4).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use Arpeggio's vetted records in the modified medical record distribution system of Ballantyne et al and Shear.

Motivation to do so would have been to help find and correct database integrity problems (see Arpeggio page 1).

As per claim 54, the modified Ballantyne et al, Shear and Arpeggio system discloses the process of verifying results in an improved accuracy or correctness of at least a portion of the information received from said one or more senders (see Arpeggio pages 1-4).

As per claim 55, the modified Ballantyne et al, Shear and Arpeggio system discloses the non-repudiated medical records are primary for treatment of said subjects (see Ballantyne et al column 12 lines 9-47).

As per claim 56, the modified Ballantyne et al, Shear and Arpeggio system discloses an integrator for reception, display, analysis and modification of said medical records available to

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be performed on a plurality of systems of health case providers, payers, clearinghouses, or oversight agencies (see Arpeggio pages 1-4).

11. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Baker and Ballantyne et al system as applied to claim 20 above, and further in view of Arpeggio.

As per claim 23, the modified Baker and Ballantyne et al system fails to disclose vetting of said medical records.

However, Arpeggio teaches vetting of records (see pages 1-4).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use Arpeggio's vetted records in the modified medical record distribution system of Baker and Ballantyne et al.

Motivation to do so would have been to help find and correct database integrity problems (see Arpeggio page 1).

As per claim 24, the modified Baker, Ballantyne et al and Arpeggio system discloses the vetted medical records have been reviewed and corrected or annotated for errors, discrepancies and anomalies (see Arpeggio pages 1-4).

As per claim 25, the modified Baker, Ballantyne et al and Arpeggio system discloses the accuracy and correctness of at least one medical record of the plurality of medical records is



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better than exists at a source site from which the medical record was obtained (see Arpeggio pages 1-4).

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. PCASSO manuals, Baker ("PCASSO: Applying and Extending State-of-the-Art Security in Healthcare Domain").

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pyzocha whose telephone number is (571) 272-3875. The examiner can normally be reached on 7:00am - 4:30pm first Fridays of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Caldwell can be reached on (571) 272-3868. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJP

Andrew Caldwell  
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